

-- REMARKS --

The present amendment replies to a First Non-Final Office Action dated January 30, 2003. Claims 1-27 are currently pending in the present application. Claims 22 and 27 have been amended herein to more particularly point out and distinctly claim the present invention. No new matter has been introduced by the amendment to claims 22 and 27.

In the First Non-Final Office Action, the Examiner rejected pending claims 1-27 on various grounds. The Applicants respond to each ground of rejection as subsequently recited herein, and respectfully request reconsideration and further examination of the present application:

- A. Claims 1-3, 6, 8-10, 12, 14, 16, and 22-27 were rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 6,066,156 to Yan .

The Applicant has thoroughly considered Examiner Baxter's remarks concerning the patentability of claims 1-3, 6, 8-10, 12, 14, 16, and 22-27 over U.S. Patent No. 6,066,156 to Yan et al. (hereinafter the "*Yan Patent*"). The Applicant has also thoroughly read the *Yan Patent*. The Applicant traverses the 35 U.S.C. §102(b) rejection of independent claims 1, 9, and 22 and independent claim 27 as amended herein because the *Yan Patent* fails to disclose, teach, or suggest each and every element of the balloon, balloon stent assemblies, and method of retaining a stent on a balloon of the present invention. Specifically, the *Yan Patent* fails to disclose, teach, or suggest the limitation of flowing a balloon outer layer portion into stent gaps when said portion is heated to a predetermined temperature.

The *Yan Patent* discloses a stent delivery catheter comprising a catheter body having a deflated balloon portion, a layer of heat sensitive adhesive disposed on the balloon portion, wherein the adhesive is tacky at and below a temperature T, and is non-tacky above T; and wherein the stent is disposed on the layer of heat sensitive adhesive (see column 2; lines 46-52).

In one embodiment of the *Yan Patent*, interstitial spaces of the stent may be at least partially filled by applying an adhesive (see column 5, lines 3-6). However, the *Yan Patent* does not disclose that heating the adhesive is necessary or even preferable for its application. As such, the *Yan Patent* does not disclose, teach, or suggest that heating of the adhesive would result in or is coupled with flowing of the adhesive into stent gaps.

In other embodiments, *Yan* discloses that adhesive may in fact be heated, but that the heating is used to accomplish the following: A) making the adhesive non-tacky to release the stent during deployment (see column 3, line 65 through column 4, line 2); B) making the adhesive non-tacky to allow the stent to facilitate stent mounting onto the balloon (see column 6, lines 51-58); or C) making the adhesive tacky for an undisclosed reason (see column 7, lines 31-34).

In embodiment A), the adhesive is heated to a predetermined temperature within the blood vessel resulting in a phase change during stent deployment (e.g., a tacky to a non-tacky state). This embodiment teaches away from a strategy of heating to cause adhesive flow into stent gaps. For example, heating is not used to retain the stent to the balloon; rather, the stent is released from the balloon as the adhesive is heated. In fact, the predetermined temperature described by *Yan* is preferably in the range of 38-47 degrees Celsius (see column 3, lines 52-54), a temperature corresponding to *in-vivo* conditions and suited for *in-vivo* stent deployment, and not generally optimal for flowing adhesive into stent gaps.

In embodiment B), the adhesive may be heated to make it non-tacky to facilitate stent mounting. Although heating may be used during or prior the stent mounting, this embodiment does not disclose that the heating is associated with any adhesive flow into stent gaps. In fact, this embodiment teaches away from heating to cause adhesive flow into stent gaps. The mounting process described by *Yan* allows “easy” alignment and adjustment of the stent after the adhesive has been heated (see column 6, lines 49-58), a process not “easily” achievable when flowing adhesive into stent gaps.

In embodiment C), a provision is made for the adhesive to alternatively become tacky once heated, however a specific application of this alternative is not discussed. Because adhesive tackiness properties are not necessarily associated with adhesive flow properties, heating the adhesive to make it tacky does not necessarily suggest that adhesive flow will result (e.g., as a function of adhesive viscosity). As such, the *Yan Patent* embodiment C) does not disclose that heating is associated with adhesive flow into stent gaps.

In contrast to the *Yan Patent*, independent claims 1 and 9 and independent claims 22 and 27 as amended of the present application each include the limitation of flowing an outer layer portion **22** into stent gaps **33** when heated to a predetermined temperature. As discussed above, this limitation is not disclosed, taught, or suggested, in the *Yan Patent*. Independent claims 1 and 9 and, as amended, independent claims 22 and 27 cannot be anticipated by the *Yan Patent* under 35 U.S.C. §102(b). Accordingly, allowance of independent claims 1 and 9 and independent claims 22 and 27 as amended is respectfully requested.

Regarding claims 2, 3, 6, 8, 10, 12, 14, 16, and 23-26, said claims depend from independent claims 1, 9, and 22. Therefore, dependent claims 2, 3, 6, 8, 10, 12, 14, 16, and 23-26 include all of the elements and limitations of independent claims 1, 9, and 22. It is therefore respectfully submitted by the Applicant that dependent claims 2-9 and 2, 3, 6, 8, 10, 12, 14, 16, and 23-26 are allowable over the *Yan Patent* for at least the same reasons as set forth above with respect to independent claims 1, 9, and 22. Allowance of dependent claims 2, 3, 6, 8, 10, 12, 14, 16, and 23-26 is respectfully requested.

Therefore, for the reasons mentioned above, withdrawal of the Rejection under 35 U.S.C. § 102(b) for claims 1-3, 6, 8-10, 12, 14, 16, and 22-27 is respectfully requested.

- B. Claims 1-21 were rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,807,327 to Green et al. in view of U.S. Patent No. 6,066,156 to Yan .

The Applicant has thoroughly considered the Examiner's remarks concerning the patentability of claims 1-21 over Green *et al.* (hereinafter the "*Green Patent*") in view of U.S. Patent No. 6,066,156 to Yan (hereinafter the "*Yan Patent*"). The Applicant has also thoroughly read the *Green* and *Yan Patents*. The Applicant traverses the 35 U.S.C. § 103(a) rejection of claims 1-21 as amended herein because the *Green* and *Yan Patents* fail to disclose, teach, or suggest each and every element, alone or in combination, of the balloon stent assemblies of the present invention.

To make a *prima facie* case of obviousness under § 103(a), all of the *claimed* elements of the invention must be taught or suggested by the prior art (MPEP § 2143.03). When evaluating claims for obviousness under § 103(a), all the limitations of the claims must be considered and given weight. Regarding independent claims 1 and 9, neither the *Green Patent* nor the *Yan Patent* disclose, teach, or suggest flowing the outer layer portion 22 into stent gaps 33 when heated to a predetermined temperature.

The Examiner states that "Green does not disclose that the outer layer portion flows into gaps..." The Applicant maintains, as discussed above, that the *Yan Patent* does not disclose, teach, or suggest flowing the outer layer portion **22** into stent gaps **33** when heated to a predetermined temperature. As this limitation is not disclosed, taught, or suggested, the cited references cannot be used to obviate independent claims 1 and 9 under § 103(a). As such, allowance of independent claims 1 and 9 is respectfully requested.

Regarding claims 2-8 and 10-21, said claims depend from independent claims 1 and 9. Therefore, dependent claims 2-8 and 10-21 include all of the elements and limitations of independent claims 1 and 9, respectively. It is therefore respectfully submitted by the Applicant that dependent claims 2-8 and 10-21 are allowable over the *Green* and *Yan Patents* for at least the same reasons as set forth above with respect to independent claims 1 and 9. Allowance of dependent claims 2-8 and 10-21 is respectfully requested.

Therefore, for the reasons mentioned above, withdrawal of the rejection under 35 U.S.C. § 103(a) for claims 1-21 is respectfully requested.

SUMMARY

Examiner Baxter's objections and 35 U.S.C. §102(b), rejection have been obviated by the amendment to independent claims 22 and 27 and above remarks corresponding to claims 1-3, 6, 8-10, 12, 14, 16, and 22-27. Examiner Baxter's 35 U.S.C. §103(a) rejections have been obviated by the above remarks corresponding to claims 1-21. The Applicant respectfully submits that claims 1-27 fully satisfy the requirements of 35 U.S.C. §§ 102, 103 and 112. In view of the foregoing amendments and remarks, favorable consideration and early passage to issue of the present application are respectfully requested.

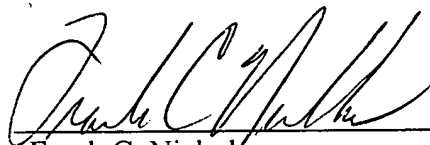
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